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# (12) United States Patent

Cherif-Cheikh

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(54)	INJE	CTION	DEV	ICE
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(75) Inventor: Roland Cherif-Chelkh, Issy les

Moulineaux (FR)

(73) Assignee: Delab, Paris (FR)

(\*) Notice:

This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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#### Related U.S. Application Data

(63)	Continuation of application No. 08/777,634, filed on Dec.
` ′	31, 1996, now Pat. No. 5,776,107.

(51)	Int. Cl.7		A61M	5/00
(52)	HC CL	6041	108. 60/	1/263

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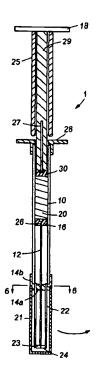
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Primary Examiner—John D. Yasko (74) Attorney, Agent, or Firm—Fish & Richardson P.C.

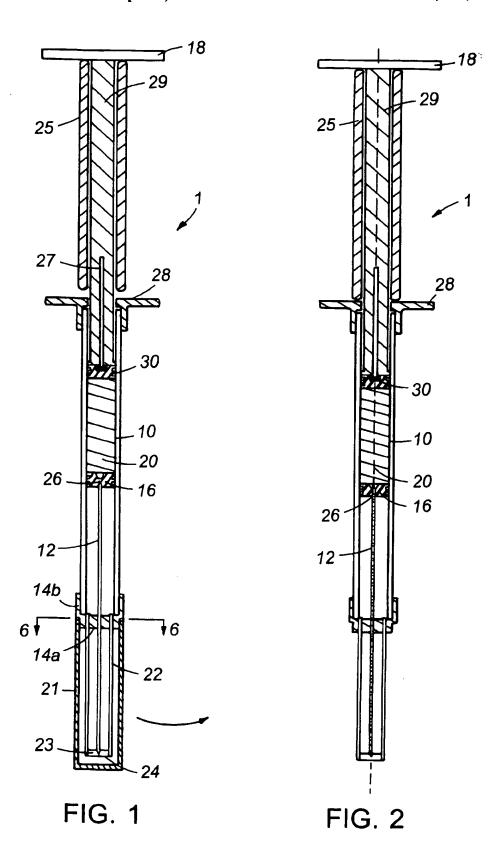
57) ABSTRACT

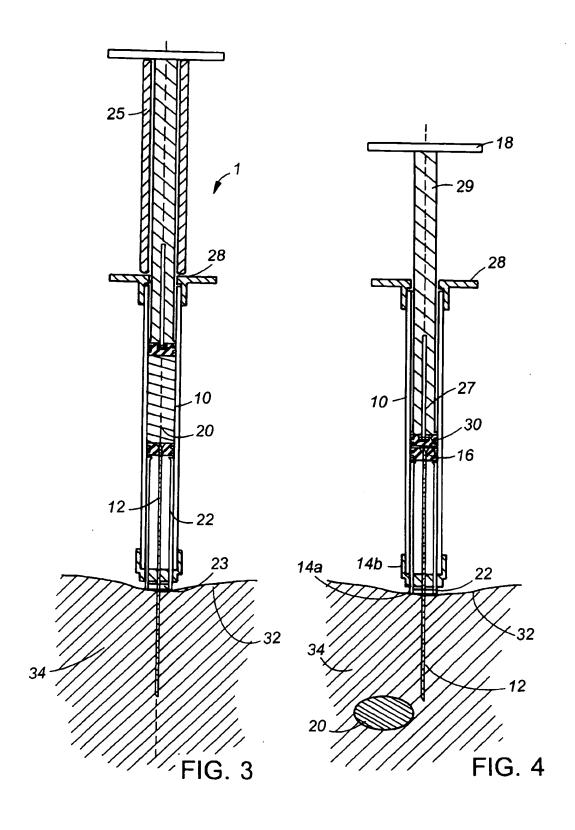
The invention features an injection device for injecting a liquid or semi-solid composition into a subject.

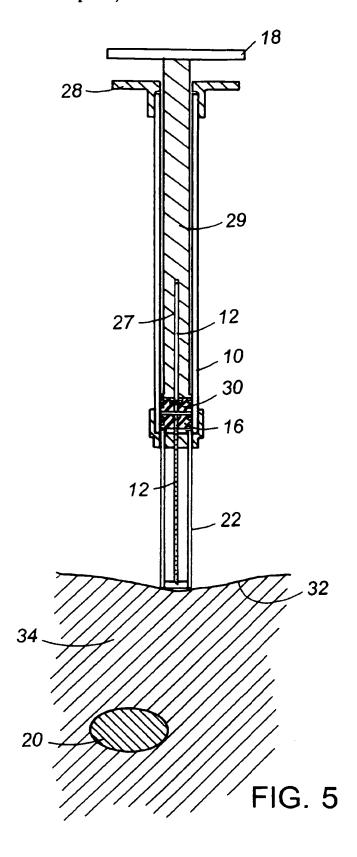
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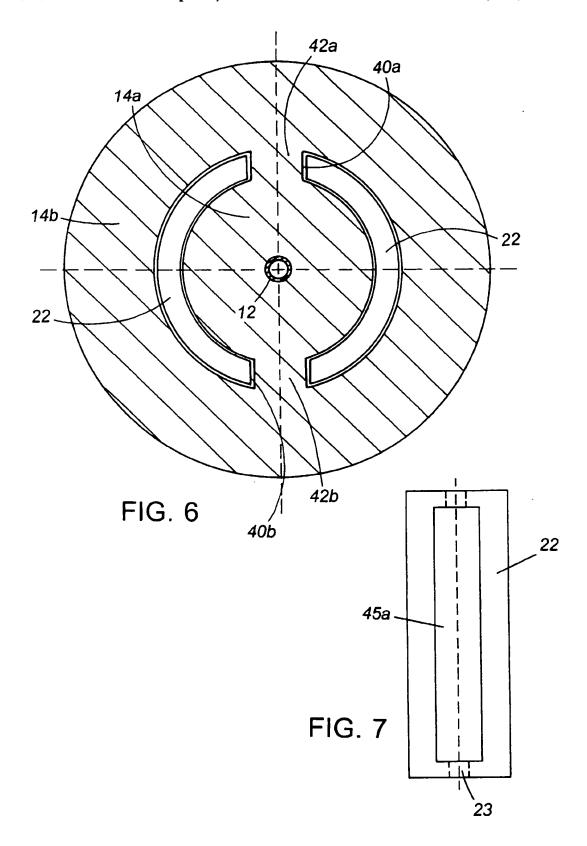


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## 1

## INJECTION DEVICE

This application is a continuation of Ser. No. 08/777,634 filed Dec. 31, 1996 now U.S. Pat. No. 5,776,107.

#### BACKGROUND OF THE INVENTION

The invention relates to a device for the parenteral administration through a needle of liquid or semi-solid drug compositions wherein the needle is protected before and after the injection.

The parenteral introduction of pharmaceutically active compounds is preferred over oral dosage for many indications, e.g., where the drug to be administered would partially or totally degrade in the gastrointestinal tract, or where there is need for a rapid biological response. The need 15 for extemporaneous preparation of such parenteral compositions is eliminated, or simplified, by the use of pre-filled administration devices in which the liquid to be injected is pre-loaded into the device (e.g., a pre-loaded syringe). Such pre-loaded devices, however, have a number of drawbacks, 20 including the inability to preserve the asepsis or sterility of the needle, as well as the general danger of using an exposed needle. To eliminate these drawbacks, it is necessary to avoid the direct exposure of the needle with the environment both prior to and following injection.

#### SUMMARY OF THE INVENTION

The invention features a comparatively inexpensive injection device with a needle for parenteral injection of liquid or semi-solid drug compositions into a subject, e.g., a mammal such as a human, wherein the needle is protected both before and after the injection.

In general, the invention features an injection device including a housing, the housing having proximal and distal ends and designed to contain a liquid or semi-solid drug 35 composition; a hollow needle, the needle affixed to the distal end of the housing and extending longitudinally within the housing; a plunger, the plunger arranged to slide within the proximal end of the housing; and a hollow sleeve, the hollow sleeve arranged to cover the needle prior to injection and 40 arranged to retract into the housing during injection; wherein the device is designed such that when the sleeve is pressed against the subject, the sleeve retracts into the housing thereby allowing the needle to penetrate the subject, and composition is forced from the housing through the needle and into the subject.

In one embodiment, the device is further designed such that when the drug composition is forced from the housing, the plunger forces the sleeve out of the housing to cover the 50 needle. In a further embodiment, the housing contains the liquid or semi-solid drug composition.

In another embodiment, the device further comprises a septum plunger, the septum plunger slidably arranged within the housing between the plunger and the distal end of the 55 housing. In a further embodiment, the device is further designed such that when the drug composition is forced from the housing, the plunger forces the septum plunger into the sleeve, and the septum plunger forces the sleeve out of the housing to cover the needle. In still a further 60 embodiment, the housing contains the liquid or semi-solid drug composition between the plunger and the septum plunger.

In still another embodiment, the housing contains a liquid and a dry drug composition, where the device is designed to 65 combine the liquid and the dry drug composition prior to injection.

The device can further include a releasable lock to inhibit the movement of the plunger into the housing. The device can also include a removable cap which covers the sleeve. The proximal end of the housing may have a flange and the plunger may also have a flange.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although methods and materials similar 10 or equivalent to those described herein can be used in the practice or testing of the present invention, the preferred methods and materials are described below. All publications, patent applications, patents, and other references mentioned herein are incorporated by reference in their entirety. In case of conflict, the present specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limit-

Other features and advantages of the invention will be apparent from the following detailed description, and from the claims.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a partial cross-sectional view of an injection device prior to use.

FIG. 2 is a partial cross-sectional view of the injection device of FIG. 1 during use.

FIG. 3 is a partial cross-sectional view of the device with the needle injected into a subject.

FIG. 4 is a partial cross-sectional view of the injection device being withdrawn from the subject with a drug composition remaining in the subject.

FIG. 5 is a partial cross-sectional view of the injection device following complete withdrawal of the needle from

FIG. 6 is a cross-section of the injection device through line 6-6 in FIG. 1.

FIG. 7 is a view of the sleeve of the injection device.

#### DETAILED DESCRIPTION

It is believed that one skilled in the art can, based on the when the plunger is forced further into the housing, the drug 45 description herein, utilize the present invention to its fullest extent. The following specific embodiments are, therefore, to be construed as merely illustrative, and not limiting.

> FIG. 1 shows injection device 1 including housing 10, having a proximal end and a distal end 14a, 14b. The distal end of housing 10 has two holes 40a and 40b partially separating the two parts 14a and 14b of the distal end (as best seen in FIG. 6). Needle 12 is attached to part 14a of the distal end. The housing 10 can be made from a rigid material such as glass, plastic, or metal. The needle 12 is hollow and double-ended, wherein its distal end, remaining outside housing 10, has a point capable of piercing the skin of a subject, and its proximal end, remaining within housing 10. is capable of piercing septum plunger 16. On the proximal end of housing 10 is a flange 28 to assist in removal of device 1 from the subject following injection.

> An sleeve 22 surrounds needle 12 so that needle 12 is not fully exposed to the environment until used. Sleeve 22 has longitudinal slots 45a and 45b along its length (see FIG. 7; slot 45b is on the back of the sleeve and is thus not shown). The two parts 14a and 14b of the distal end are joined by radially extending connecting members 42a and 42b (see FIG. 6). Connecting members 42a and 42b, respectively,

slide through slots 45a and 45b in sleeve 22, while sleeve 22 slides through boles 40a and 40b in housing 10. Sleeve 22 can be made of suitably rigid material, such as metal, glass, or plastic. Scal 24 covers the opening 23 of sleeve 22 to maintain the sterility of needle 12 and prevent sleeve 22 from unintentionally retracting into housing 10 through holes 40a and 40b prior to injection.

Seal 24 can be made of a thin material, such as plastic or wax, which is easily penetrated by needle 12 during injection. A similar seal can also cover slots 45a and 45b in sleeve 10 22, to further protect the sterility of needle 12.

Septum plunger 16, contained within housing 10, includes a bore 26, in which needle 12 rests prior to subsequently piercing septum plunger 16. A liquid or semi-solid composition 20 is isolated in housing 10 between the septum plunger 16 and the plunger tip 30, attached to plunger 29. Septum plunger 16 and plunger tip 30 may be made of non-rigid, solid material such as rubber, which allows septum plunger 16 and plunger tip 30 to slide within housing 10 but still maintain sufficient friction with the inner sides of housing 10 to seal composition 20 within housing 10.

The proximal end of plunger 29 has a thumb flange 18 to assist in the depression of plunger 29 into housing 10, and the distal end of plunger 29 has a longitudinal bore 27 to receive needle 12 following injection of composition 20 out and through needle 12. Plunger 29 can be made from a rigid material, such as metal or plastic. A removable lock 25 may be placed between flange 18 and flange 28 to inhibit the further depression of plunger 29 into housing 10 after activation of device 1, i.e., after the housing 10 is filled with a drug composition and the proximal end of the needle is pierced through septum plunger 16. A removable cap 21 can also be used to protect both needle 12 and sleeve 22 prior to use. Both cap 21 and lock 25 can be made from suitable rigid material such as plastic, metal, or rubber.

FIG. 2 shows device 1 wherein plunger 29 has been pressed into housing 10 to activate device 1 as follows. When plunger 29 is depressed, plunger tip 30, composition 20, and septum plunger 16 are displaced toward the distal end of housing 10. Septum plunger 16 is pierced at bore 26 by needle 12. As a result, the proximal end of needle 12 is exposed to composition 20. Device 1 is now in an activated state. Lock 25, by contacting both flange 18 and flange 28, inhibits the further displacement of composition 20 from housing 10 through needle 12 following activation of device 1, i.e., composition 20 is allowed to fill needle 10, but lock 25 inhibits significant release of composition 20 through needle 10.

FIG. 3 shows device 1 wherein needle 12 has penetrated 50 skin 32 of the subject being treated. As device 1 is pressed against skin 32, sleeve 22 is retracted into housing 10, through holes 40a and 40b, by the force of pressure against skin 32. Needle 12 passes through sleeve 22 at opening 23. As shown, needle 12 has penetrated through skin 32 into the 55 subcutaneous layer 34.

FIG. 4 shows device 1 wherein lock 25 has been removed and plunger 29 has been depressed which moves plunger tip 30 toward septum plunger 16, thereby injecting composition 20 into subcutaneous layer 34 through needle 12. Once 60 composition 20 has been injected and plunger tip 30 rests against septum plunger 16, housing 10 is moved away from skin 32 by exerting pressure against the lower part of the flange 28 while simultaneously exerting opposing pressure on flange 18 of plunger 29. This relative movement of the 5 plunger 29 and housing 10 causes plunger tip 30 to force septum plunger 16 against sleeve 22 as both plunger tip 30

and septum plunger 16 slide toward parts 14a and 14b of the distal end of housing 10, which in turn forces sleeve 22 out of housing 10 through holes 40a and 40b. As plunger tip 30 and septum plunger 16 are moved toward distal end of housing 10, needle 12 penetrates septum plunger 16, plunger tip 30, and enters bore 27 in plunger 29.

FIG. 5 shows needle 12 fully withdrawn from skin 32 and sleeve 22 fully covering needle 12. Composition 20 remains in the subcutaneous layer of the patient. As can also be seen in FIG. 5, the proximal end of needle 12 has been pushed through septum plunger 16 and plunger tip 30 and remains in bore 27 of plunger 29.

FIG. 6 is a cross-sectional view of FIG. 1 at 6—6. FIG. 6 shows holes 40a and 40b in housing 10. Radially extending connecting members 42a and 42b extend through slots 45a and 45b, respectively, to connect parts 14a and 14b of the distal end. Needle 12 is fixed to central part 14a of the distal end, and sleeve 22 can slide through holes 40a and 40b. FIG. 7 shows an isolated sleeve 22 having slots 45a and 45b (45b is not shown but positioned directly opposite to slot 45a on the other side of sleeve 22) and opening 23. Radially extending connecting members 42a and 42b, respectively, slide through slots 45a and 45b.

Composition 20 is a liquid or a viscous semi-solid composition containing a drug. The drug of composition 20 can be any drug capable of being parenterally administered as a liquid or a semi-solid. For example, the drug can be a vaccine, a peptide, a protein, or a small chemical entity. Examples of suitable drugs include insulin and heparin. For drugs which are not stable in liquids over an extended period of time, the liquid and the dry drug can be stored in separate chambers within housing 10. The device can be designed such that the liquid and the dry drug are combined together just prior to injection.

For example, the chamber created between septum plunger 16 and plunger tip 30 (e.g., in FIG. 1) in housing 10 can be separated into two separate parts by a fixed wall or film that can be punctured, e.g., by pressure of the plunger 29 on the plunger tip 30, or a puncturing means. Alternatively, the two parts of the chamber can be separated by a moving wall or septum. In this case, the top or proximal part of the chamber above the moving septum contains the liquid portion of the composition, and the distal part of the chamber contains the solid, e.g., powder, portion of the composition. When plunger 29 is pushed down, it applies pressure to the plunger tip 30, which applies pressure to the liquid portion of the composition. This, in turn, applies pressure on the moving septum, causing it to move in a distal direction. The housing is designed with a liquid bypass (e.g., a bulge or passage in the housing wall) in a location that initially prevents passage of liquid from one part of the chamber to the other, but when the moving septum reaches a specific location, the bypass allows the liquid to pass from the top part of the chamber into the lower or proximal part of the chamber on the other side of the moving septum.

To maintain sterility, the device of the invention can be stored in a conventional blister pack prior to use.

#### OTHER EMBODIMENTS

It is to be understood that while the invention has been described in conjunction with the detailed description thereof, that the foregoing description is intended to illustrate and not limit the scope of the invention, which is defined by the scope of the appended claims. Other aspects, advantages, and modifications are within the claims.

What is claimed is:

- 1. An injection device for injecting a liquid or semi-solid composition into a subject, the device comprising:
  - a hollow housing having a proximal end and distal end, said housing being configured to contain a liquid or 5 semi-solid composition;
  - a hollow needle, said needle affixed to the distal end of the housing and extending longitudinally within said housing:
  - a plunger arranged to slide within the proximal end of the housing; and
  - a hollow sleeve slidably connected to the distal end of the housing and arranged to cover the needle prior to injection and to retract into the housing during injection;
- wherein the device is configured such that when the sleeve is pressed against the subject, the sleeve retracts into the housing thereby allowing the needle to penetrate into the subject, and when the plunger is pushed

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into the housing, the composition is pushed from the housing through the needle and into the subject.

2. An injection device of claim 1, wherein the device is further configured such that when the composition is pushed out of the housing, the plunger moves the sleeve out of the housing to cover the needle.

3. A device of claim 1, wherein the housing contains the liquid or semi-solid composition.

4. A device of claim 2, wherein the housing contains the liquid or semi-solid composition.

5. A device of claim 1, wherein the device further comprises a releasable lock to inhibit movement of the plunger into the housing.

6. A device of claim 1, wherein the device comprises a removable cap which covers the sleeve.

7. A device of claim 1, wherein the proximal end of the housing comprises a flange.

8. A device of claim 1, wherein the plunger comprises a flange.

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# United States Patent [19]

# Cherif-Cheikh

[11] Patent Number:

5,695,463

[45] Date of Patent:

Dec. 9, 1997

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[51]	Int. CL°.	A61M 31/90	00961	6/1996	WIPO.	
[52]	U.S. Cl	604/60; 604/167; 604/171;		_		
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[20]	[58] Field of Search604/57-61, 110, 604/117, 167, 158, 192, 194, 197, 198,		Astorney, Agent, or Firm-Fish & Richardson P.C.			
		218, 228, 171, 195, 264, 274, 199	[57]		ABSTRACT	
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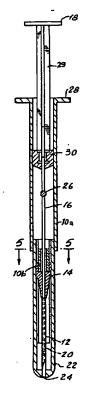
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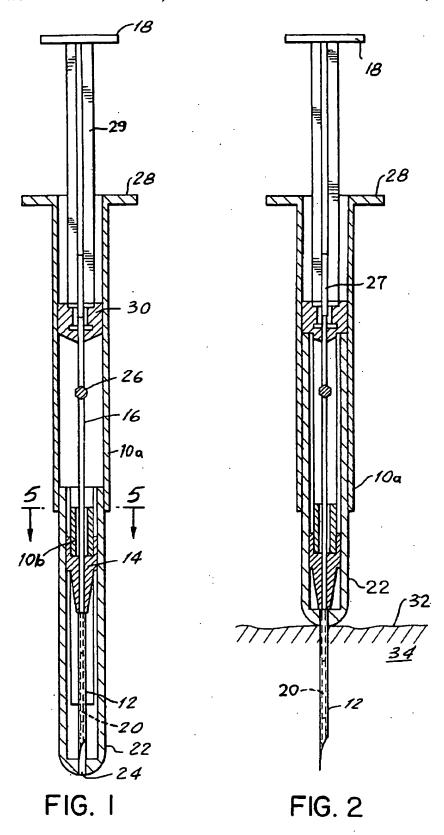
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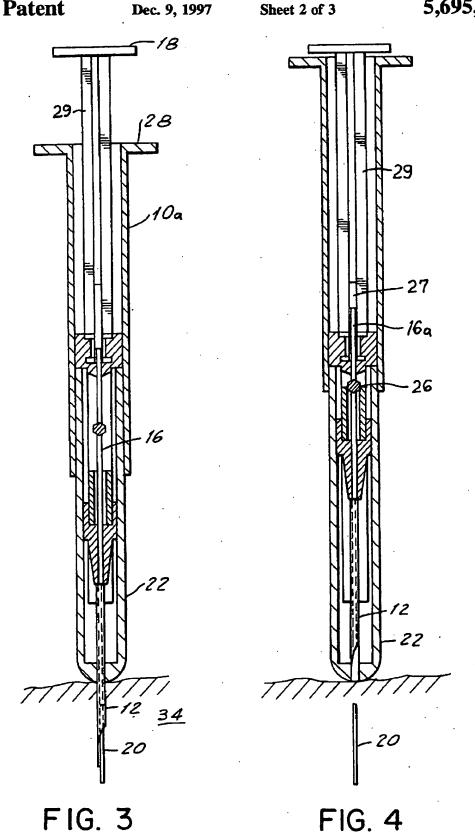
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4,774,091	9/1988	Yamahira .
4,820,267	4/1989	Harman .
4,846,793	7/1989	Leonard et al

An injection device for intramuscular or subcutaneous injection of solid or semi-solid medicaments is disclosed. The device includes main body member having a needle attached thereto. A protective sleeve covers the needle and retracts into the main body member when the device is pressed against the skin of a patient. A plunger with an attached rod maintains the medicament in the patient as the needle is withdrawn.

16 Claims, 3 Drawing Sheets







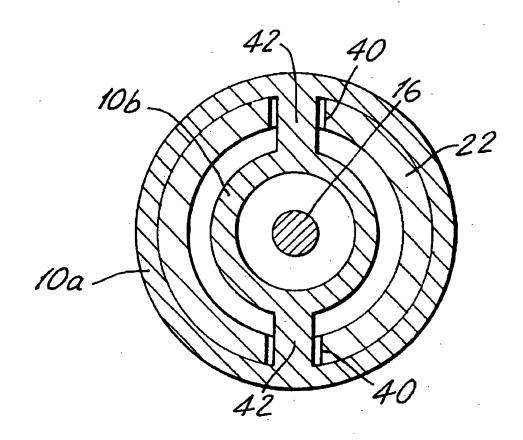


FIG. 5

#### SAFETY INJECTION DEVICE

This is a continuation of application Ser No. 08/312,893, filed Sep. 27, 1994, now abandoned.

#### BACKGROUND OF THE INVENTION

The present invention relates to injection devices and, in particular, to a device for the intramuscular or subcutaneous injection of a pharmaceutically active compound.

The parenteral introduction of pharmaceutically active compounds is preferred over oral dosage in many applications. For example, when the drug to be administered would partially or totally degrade in the gastrointestinal tract, parenteral administration is preferred. Similarly, where there is need for rapid response in emergency cases, parenteral administration is preferred over oral administration.

Thus, while parenteral administration is desirable in many applications, as it is currently practiced it has substantial drawbacks. Probably the biggest drawback is the discomfort 20 which it causes the patient to whom the drug is being administered. Parenteral preparations generally contain a large volume of liquid in which the drug is suspended or dissolved. Ratios of active ingredient to carrier commonly run from 1:100 to 1:1000. When the active ingredient is 25 poorly soluble or difficult to suspend in the carrier, or when the active ingredient has to be administered at high doses, or in both instances, a fairly large volume of liquid must be injected. Both the size of the needle and the volume of liquid being injected cause parenteral administration to be more or 30 less painful, and at least disagreeable, for most people. Furthermore, depending on its nature, the carrier itself may be a cause of pain.

A further disadvantage to administration of drugs in a liquid carrier is that the drugs are frequently not stable in the liquid. Therefore, the liquid and drug must be mixed substantially contemporaneously with injection. This can be of substantial disadvantage where, for example, many hundreds of people must be treated over a course of days in order to stem an epidemic.

Drugs in solid form rather than liquid form have been used for prolonged or controlled release formulations. When the formulation is not a microstructure or a powder that can be injected in suspension form, with a liquid and a standard syringe, the formulation is usually an implant or a rod which can be injected directly via a trocar, see for example European Patent Application Publication No. 0292936. However, trocars and the device as set forth in the cited European Patent have some disadvantages. When the formulation is a prolonged or controlled formulation, the formulation must contain the daily dose of drug multiplied by the number of days of activity of the drug and the amount of carrier necessary to control the rate of delivery of that drug. Thus this formulation, which is in the needle, requires a needle significantly larger than ordinary needles used with syringes and this results in a painful injection.

#### SUMMARY OF THE INVENTION

The applicant has now discovered a comparatively inexpensive device for the ready administration of solid or substantially solid drugs by the parenteral route wherein the drugs are intended to be immediately assimilated by the body.

Because the quantity of drug is just the amount needed for 6s an immediate effect and because there is no need for carriers to control function, the needle can be as small as ordinary

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needles. The drug is stable because it is in solid form and, thus, no contemporaneous mixing is needed. The injection is substantially painless because the needle size for the injected volume is dramatically reduced as compared to the size needed for liquid injection. The risk of contamination can be reduced because there is no pre-manipulation of the injectable formulation before making the injection. A seal can be fitted on the tip of the injection member so that there is complete sterility until injection into the skin.

Finally, because there is no volume of liquid to inject, the procedure is simplified.

The applicants herein filed a co-pending application Ser. No. 08/304,274 on Sep. 12, 1994 entitled NEEDLELESS PARENTERAL INTRODUCTION DEVICE, the teaching of which is hereby incorporated by reference. The device in this co-pending application comprises a housing and a plunger. The plunger pushes a solid medicament out of a bore in the housing and directly into the patient. This device works very well for drugs which can be made structurally strong enough to penetrate the skin. However, it has been found that there are some drugs which cannot be made structurally strong enough. While such drugs could be combined with a structurally strong carrier, there are instances where the use of such a carrier is undesirable.

In accordance with the present invention the applicants have developed a device similar to the NEEDLELESS PARENTERAL INTRODUCTION DEVICE except that in the instant case the device includes a needle. Unlike past devices, however, the device of the present invention has a needle which is never exposed to the outside elements. Thus it can never pick up airborne contaminants, nor can it inadvertently scratch someone, such as a hospital worker. This aspect is especially important for treatment of mentally unstable patients.

These and other aspects of the present invention may be more fully understood with respect to the drawings.

### BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 shows the device at rest.

FIG. 2 shows the device with the needle injected into the patient.

FIG. 3 shows the needle being withdrawn with the medicament remaining in the patient.

FIG. 4 shows complete withdrawal of the needle from the patient.

FIG. 5 shows a cross-section through line 5—5 of FIG. 1. Referring first to FIG. 1 there is shown main body member 10a, 10b which is attached to needle 12 through coupling means 14. A rod 16 is guided into needle 12 and abuts medicament 20 which is positioned in needle 12. A sleeve 22 surrounds needle 12 so that needle 12 is not exposed until used. Sleeve 22 is provided with one or more slots 40 (see FIG. 5) along its length so that main body members 10a and 10b can be joined by radially extending connecting members 42. A seal 24 covers the opening 23 and the slots 40 of sleeve 22 in order to maintain the sterility of needle 12 and medicament 20. The seal is preferably of easily friable material such as wax. Rod 16 includes a bulb 26 which serves as a stop for travel of the rod 16. Main body member 10 has a flange 28 to assist in removal of the device after injection. Rod 16 is attached to a plunger 29 which has a top thumb flange 18. A guide 30 is attached to plunger 29 and is positioned in main body member 10 to guide plunger 29 and rod 16.

FIG. 2 shows the device of FIG. 1 wherein needle 12 has penetrated the skin 32 of the person being treated. As shown,

needle 12 has penetrated through the skin 32 into the subcutaneous layer 34. As the device of FIG. 1 is pressed against the skin 32, sleeve 22 is retracted into main body member 10 by the force of pressure against the skin 32.

At this point, and as shown in FIG. 3, main body member 10 is moved in an upward direction by exerting finger pressure against the lower part of flange 28 while simultaneously exerting opposing pressure with the thumb on flange 18 of plunger 29. This relative movement of the plunger 29 and the main body member 10 causes the needle 12 to retract  $^{10}$ into sleeve 22 thus leaving medicament 20 in the subcutaneous layer 34 of the patient.

FIG. 4 shows the needle 12 fully withdrawn into sleeve 22 and with medicament 20 remaining in the subcutaneous upper portion 16a of rod 16 has been pushed into a bore 27 in plunger 29 by the action of coupling means 14 against bulb 26 of rod 16.

FIG. 5 is a cross-sectional view of FIG. 1 at 5-5. FIG. 20 mammal. 5 shows slots 40 in sleeve 22. Radially extending connecting members 42 extend through the slots 40 to join main body member 10a with main body member 10b.

As will be appreciated from the foregoing drawings and description, the only time that the needle came out of its 25 flange. protective sleeve was when it was already abutted against the patient's skin. At no time is the needle ever exposed to the air where it could become contaminated or where it might inadvertently scratch someone.

Turning now to the medicament 20, it is preferred that it 30 be solid or semi-solid. It is preferred that the device of the present invention be used with a medicament that is not strong enough to penetrate the skin; however, in some applications, it is acceptable for the medicament to have such strength. The amount of carrier, if present, should be as 35 small as possible. As a general rule, the amount of active ingredient in the medicament 20 is at least 20% and is preferably above 50%. With suitable medicaments which will hold a shape, the amount of medicament can be up to 100%. The medicament may be prepared by conventional 40 techniques such as compression, thermofusion or extrusion. Compression suitably consists of a tabletting process in which a microtablet is formed. The diameter of the medicament 20 may be up to 2 mm but is preferably from about in length. The diameter of the rod 16 is preferably about the same diameter as the diameter of the medicament 20. The inside diameter of the needle 12 is preferably just slightly larger than the diameter of the medicament. It is preferred that the needle 12 and rod 16 be metallic, notably stainless 50 a medicament. steel; the balance of the components can be relatively inexpensive plastic materials.

It will be understood that the claims are intended to cover all changes and modifications of the preferred embodiments of the invention herein chosen for the purpose of illustration 55 medicament. which do not constitute a departure from the spirit and scope of the invention.

What is claimed is:

- 1. An injection device for injecting a solid or semi-solid medicament parenterally into a mammal, said device including a main body member, a hollow needle affixed to said main body member, a plunger being slidably positioned in said main body member, a rod within said needle, said rod extending through said main body member and said rod being affixed to said plunger, and a hollow sleeve which covers said needle prior to injection, said sleeve being slidably positioned in said main body member, and wherein when said device is pressed against a mammal said sleeve retracts into said main body member thereby exposing said needle and allowing said needle to penetrate said mammal, wherein when said plunger is pushed into said main body layer 34 of the patient. As can also be seen in FIG. 4, the said main body member thereby withdrawing the needle from said mammal, and wherein said plunger and rod are operative to push the medicament through said needle into said mammal as the needle is being withdrawn from said
  - 2. The device of claim 1 wherein said rod includes a bulb which functions as a stop for said rod when said plunger is pushed into said main body member.
  - 3. The device of claim 2, wherein said plunger includes a
  - 4. The device of claim 3, wherein said main body member includes a flange.
  - 5. The device of claim 4, wherein said sleeve includes an opening covered by a seal operative to maintain the sterility of the needle.
  - 6. The device of claim 4, wherein said needle contains a medicament.
  - 7. The device of claim 2, wherein said needle contains a medicament.
  - 8. The device of claim 2, wherein said bulb contacts said main body member.
  - 9. The device of claim 2, wherein said sleeve includes an opening covered by a seal operative to maintain the sterility of the needle.
  - 10. The device of claim 1 wherein said main body member includes a flange.
  - 11. The device of claim 10, wherein said plunger includes a flange.
- 12. The device of claim 10, wherein said sleeve includes 0.25 to about 0.5 mm in diameter and about 1 to about 3 cm 45 an opening covered by a seal operative to maintain the sterility of the needle.
  - 13. The device of claim 1 wherein said plunger includes a flange.
  - 14. The device of claim 13, wherein said needle contains
  - 15. The device of claim 1 wherein said sleeve includes an opening covered by a seal operative to maintain the sterility of the needle.
  - 16. The device of claim 1 wherein said needle contains a